REMARKS

Claims 1, 2, 5-7, 10-12, and 15-23 stand rejected. Claims 16-17 have been objected to. Claims 16-17 have been amended.

Claim Objections

Claims 16-17 have been objected to for failing to include the objective terminology which describes the trademarked product Tween 80. Claims 16-17 have been amended to correct this deficiency.

35 U.S.C. § 103(a) Rejections

Claims 1, 2, 5-7 and 10 stand rejected under 35 U.S.C. 103(a) for purportedly being unpatentable over Komer U.S. Patent No. 5,773,422 ("Komer") in view of Huet et al., U.S. Patent No. 6,482,425, ("Huet"). Applicant respectfully disagrees and in view of the following remarks request that the Examiner reconsider and withdraw the rejection.

Applicant respectfully submits that in order for a claim to be found obvious, "the prior art reference (or references when combined) must teach or suggest all the claim limitations." MPEP 706(j). The Office Action contends that Komer discloses a pharmaceutical composition comprising ivermectin, propylene glycol and poly sorbate 80 and benzyl alcohol but does not disclose the addition of ethanol or isopropanol. The Office Actions further asserts that the Applicant has

not shown "that N-methylpyrrolidone disclosed by Komer would materially affect the basic and novel characteristic(s) of the claimed solution." Applicant respectfully disagrees. The Applicant has discovered a novel aqueous formulation of Ivermectin that is stable and palatable. Applicant's claimed pharmaceutical solutions "consists essentially of" ivermectin, propylene glycol and poly sorbate 80 and benzyl alcohol and do not require N-methylpyrrolidone or 2-pyrrolidone. This limitation is not taught in Komer. In Komer, each and every pharmaceutical solution disclosed includes either N-methylpyrrolidone or 2-pyrrolodone as necessary components to dissolve the invermectin. Komer requires a pyrrolidone as a solubilizer. The solutions of the instant invention do not require a pyrrolidone as a solubilizer. Clearly the used of a pyrrolidone, as required by Komer, would "materially affect the basic and novel characteristic(s) of the claimed solution." As such, Komer fails to teach or suggest the claimed invention, which is limited to the claimed essential ingredients plus any compounds present in impurity level concentrations. Huet does not compensate for Komer's deficiencies.

The Examiner contends that Huet teaches that benzyl alcohol, ethanol and isopropanol can interchangeably be used in invermectin containing compositions. But Huet fails to teach a pharmaceutical composition limited to the claimed essential ingredients and as such one of skill in the art would have no motivation to remove N-methylpyrrolidone from Komer's compositions. As

stated above, in order for a claim to be found obvious the combined prior art references must "teach or suggest all the claim limitations." MPEP 706(j). As such, the combination of Komer and Huet fails to render the claimed invention obvious.

Claims 10-12, 15 and 16 stand rejected under 35 U.S.C. 103(a) for purportedly being unpatentable over Komer. Applicant respectfully disagrees and in view of the following remarks requests that the Examiner reconsider and withdraw the rejection of the claims.

Claim 10 depends on claim 6, which requires that the pharmaceutical solution consists essentially of Ivermectin, 10-99% v/v isopropyl alcohol, propylene glycol and polysorbate 80. As stated above, Komer only teaches pharmaceutical solutions using N-methylpyrrolidone or 2-pyrrolodone as a primary solvent to dissolve Ivermectin and as such fails to teach or suggest each limitation of the claimed invention. Applicant's claimed pharmaceutical solutions consist essentially of particular components and do not require N-methylpyrrolidone or 2-pyrrolidone. In contrast, each and every pharmaceutical solution disclosed by Komer also includes either N-methylpyrrolidone or 2-pyrrolidone as necessary components to dissolve the invermectin. Furthermore, Applicant's claimed pharmaceutical compositions comprise 10-99% isopropyl alcohol, in addition to propylene glycol and polysorbate 80. Komer's Examples 14 and 17 and Col. 3, lines 6-45 do not disclose isopropyl alcohol. As such, Komer

fails to teach or suggest Applicant's claimed invention, which consists essentially of ivermectin, 10-99% v/v isopropyl alcohol, propylene glycol and polysorbate 80 plus any compounds present in impurity level concentrations. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of claims 10-12, 15 and 16 under 35 U.S.C. 103 based on Komer.

Regarding claims 11, 12, and 15, as discussed above, each and every pharmaceutical solution disclosed by Komer also includes either N-methylpyrrolidone or 2-pyrrolidone as necessary components to dissolve the invermectin. Applicant's claimed pharmaceutical solution consists essentially of particular components and does not require N-methylpyrrolidone or 2-pyrrolidone. As such, Komer fails to teach or suggest the claimed invention and Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 11, 12 and 15 under 35 U.S.C. 103 in view of Komer.

Regarding the rejection of claim 16, as discussed above, each and every formulation disclosed by Komer was prepared using either N-methylpyrrolidone or 2-pyrrolidone as necessary components to dissolve the invermectin. Applicant's method as claimed consists of particular steps that do not include using either N-methylpyrrolidone or 2-pyrrolidone as necessary components to dissolve the invermectin and Komer does not suggest excluding the step of dissolving ivermectin in N-methylpyrrolidone or 2-pyrrolidone from the method. As such Komer does not render Applicant's invention obvious and Applicant

respectfully requests that the Examiner reconsider and withdraw the rejection of claim 16 under 35 U.S.C. 103 in view of Komer.

Claims 17, 18, 22 and 23 stand rejected under 35 U.S.C. 103(a) for purportedly being unpatentable over Komer in view of Lacy et al. U.S. Patent No. 5,645,856 ("Lacy"). Applicant respectfully disagrees and in view of the following remarks and amendments to the claims requests that the Examiner reconsider and withdraw the rejection of the claims.

As discussed above, each and every pharmaceutical solution disclosed by Komer was prepared using either N-methylpyrrolidone or 2-pyrrolidone as necessary components to dissolve the invermectin. Applicant's methods as claimed consist of particular steps that do not include using either N-methylpyrrolidone or 2-pyrrolidone to dissolve the invermectin and Komer does not suggest excluding N-methylpyrrolidone or 2-pyrrolidone from the method. Lacy does not compensate for Komer's deficiencies. Lacy merely provides a list of sweeteners (Col. 14, lines 2-3). As such Komer alone or in combination with Lacy does not render Applicant's invention obvious. Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claim 16 under 35 U.S.C. 103(a) over Komer in view of Lacy.

Claims 19-21 stand rejected under 35 U.S.C. 102(b) for purportedly being anticipated by, or in the alternative, under 35 U.S.C. 103(a) for purportedly being obvious over Komer.

The Examiner contends that if there are differences in amounts of the components present in the Komer formulations and the claimed compositions, such difference would appear minor in nature and the claimed compositions would be prima facie obvious from Komer's disclosure. Applicant respectfully disagrees.

The Examiner acknowledges that the claims are limited to the terminology "consisting essentially of" but contends that Applicant failed to show that N-methylpyrrolidone present in the formulation of Example 14 and 17 would materially affect the basic and novel characteristics of the claimed invention (Office Action page 4). However, Komer's statements of the unexpected solubility of avermectins in N-methylpyrrolidone and the advantages of including N-methylpyrrolidone in his invermectin formulations (Col. 2, lines 47-61) demonstrate that one of skill in the art believes that N-methylpyrrolidone materially affects the basic and novel characteristics of those formulations. Therefore, one skilled in the art would also expect N-methylpyrrolidone to affect the basic and novel characteristics of the claimed invention. As such, the term "consisting essentially of" excludes N-methylpyrrolidone from the claimed invention.

Komer does not teach or suggest pharmaceutical compositions consisting essentially of ivermectin, propylene glycol and polysorbate 80 and therefore does not anticipate or render the claimed invention obvious. In view of the foregoing remarks, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 19-21 under 35 U.S.C. 102(b), or in the alternative, under 35 U.S.C. 103(a) for purportedly being anticipated by, or obvious over, Komer.

CONCLUSION

Applicant believes the present paper to be a complete and thorough response to the Final Office Action. In view of the foregoing amendments and remarks, the application is respectfully submitted to be in condition for allowance. Accordingly, a timely favorable action is earnestly solicited.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #101918.56959C1).

Respectfully submitted,

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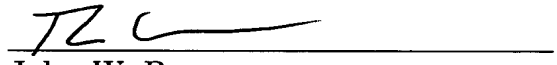

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